UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
KANSAS CITY DIVISION

ELENA MYERS and CHRIS MYERS, Plaintiffs, v. COOK GROUP, INC.; COOK INCORPORATED; COOK BIOTECH, INC; COOK UROLOGICAL INCORPORATED; COOK MEDICAL INC.; and BOSTON SCIENTIFIC CORPORATION; Defendants.	COMPLAINT AND JURY DEMAND No.

Plaintiffs, by and through their undersigned counsel, bring this Complaint for damages against Defendants and in support thereof state the following:

1. This is a device tort action brought on behalf of the above named Plaintiffs arising out of the negligence, negligent misrepresentation, breach of warranty and strict liability of the Defendants in their manufacture, promotion, distribution, sale and/or provision of incomplete, inaccurate information related to their transvaginal mesh product. As a result, Plaintiff ELENA MYERS suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff CHRIS MYERS, spouse, has also been seriously damaged as a result of the Defendants' wrongful conduct, suffering a loss of his spouses' companionship, care, guidance and advice. The Plaintiffs respectfully seek all damages to which they may be legally entitled.

I. PARTIES

2. Plaintiffs ELENA MYERS and CHRIS MYERS ("Plaintiffs") are, and were, at all relevant times, residents of Alabama.

3. Defendant Cook Group, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 750 N. Daniels Way, Bloomington, Indiana 47404-9120. Cook Group Incorporated was founded to help manage financial, legal and regulatory issues that emerged as the COOK companies expanded in the United States and abroad. http://www.cookmedical.com/profile.do?id=profile_cookgroup All acts and omissions of Cook Group, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Group, Inc. did business in Missouri.

4. Defendant Cook Incorporated is a corporation organized under the laws of Indiana, with a principal place of business at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana 47402. Cook Incorporated is also on the forefront of developing next generation technologies that advance combination drug/device and biologic/device design concepts. http://www.cookmedical.com/profile.do?id=profile_cookinc All acts and omissions of Cook Incorporated, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Incorporated, Inc. did business in Missouri.

5. Defendant Cook Biotech, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 1425 Innovation Place, West Lafayette, Indiana 47906. Cook Biotech was created to develop and manufacture biomaterials from natural tissue sources for use in medical products. The company conducts research, development and

manufacturing operations in a state-of-the-art facility. Cook Biotech operates its own processing and production line where natural tissues are transformed into acellular biomaterials. In cooperation with university researchers, Cook Biotech has developed a line of products that can remodel native tissues using a biomaterial made from porcine small intestinal submucosa (SIS). Several FDA-cleared products using this technology to dress wounds or to surgically repair soft tissues are currently available from COOK and its distributors. Numerous potential medical applications for products made from SIS and other natural tissues are under development. http://www.cookmedical.com/profile.do?id=profile_biotech All acts and omissions of Cook Group, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Biotech, Inc. did business in Missouri.

6. Defendant Cook Urological Incorporated is a corporation organized under the laws of Indiana, with a principal place of business at 1100 West Morgan Street, P.O. Box 227, Spencer, IN 47460 Cook Urological is the global sales and marketing headquarters for the Urological and Women's Health strategic business units. Cook Urological was established to provide professionals in urologic healthcare with minimally invasive diagnostic and therapeutic technology. The company is recognized worldwide for innovation in stone management, diagnostic and therapeutic products for the urinary system, and biomaterials for the treatment of stress urinary incontinence. http://www.cookmedical.com/profile.do?id=profile_uro All acts and omissions of Cook Urological Incorporated as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Group, Inc. did business in Missouri.

7. Defendant Cook Medical, Inc. is a corporation organized under the laws of Indiana, with a principal place of business at 1025 W. Acuff Road, Bloomington, Indiana 47402-4195. Cook Medical Incorporated was established to offer a synchronized service for the efficient purchase and distribution of all Cook medical devices. With particular focus on lowering supply chain costs, the company coordinates price file access, purchase orders, ship points and accounts payable. http://www.cookmedical.com/profile.do?id=profile_cmi All acts and omissions of Cook Medical, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership. At all times material hereto, Cook Medical, Inc. did business in Missouri.

8. Upon information and belief, the Cook Defendants individually or collectively make, use, offer for sale, sell in the United States, and/or import into the United States products used to treat pelvic organ prolapse and stress urinary incontinence including the Surgisis Biodesign system or line of pelvic products and related delivery devices.

9. Upon information and belief, Defendant Cook Group, Inc. is the parent company for all other named Defendants and did the following through its subsidiaries named herein: designed; secured clearance for sale; manufactured; labeled; marketed; distributed; sold; benefited financially from the sale; and placed into the stream of commerce the products implanted in Plaintiffs. Defendants, as such, are individually, jointly and severally liable to Plaintiffs.

10. Upon information and belief, and upon review of the Cook Defendants' own combined website, Plaintiffs assert that the following Defendants' participated in placing the product implanted in Plaintiff into the stream of commerce causing her injuries: Cook Group,

Inc. is the parent and nerve center of the Cook operations which, through its subsidiaries designed, tested, sought regulatory clearance, marketed, advertised, labeled, distributed and sold the subject medical device; Defendant Cook Incorporated participated in the development of the subject medical device; Defendant Cook Biotech, Inc. developed, with the aid of other co-Defendants, manufactured, sought regulatory clearance, marketed, advertised, labeled, distributed and sold the subject medical device; Defendant Cook Urological Incorporated with the aid of other co-Defendants, manufactured, sought regulatory clearance, marketed, advertised, labeled, distributed and sold biomaterials for the treatment of stress urinary incontinence including the subject medical device; and Defendant Cook Medical, Inc. were the central and key agent in the distribution of Plaintiff's medical device.

11. Defendant Boston Scientific is a Massachusetts corporation with its principal place of business in Massachusetts. At all times material hereto, Boston Scientific Corporation did business in Missouri.

12. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

13. Defendants share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as “Defendants”.

II. JURISDICTION AND VENUE

14. Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

15. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

16. Venue is proper in this Court pursuant to 28 U.S.C. §1391(a)-(c) by virtue of the fact that Defendants' products are sold to and consumed by individuals in the State of Missouri thereby subjecting Defendants to personal jurisdiction in this action and making it a "resident" of this judicial district.

17. Defendants conducted substantial business in the State of Missouri and in this District, distribute Pelvic Mesh Products in this District, receive substantial compensation and profits from sales of Pelvic Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District.

18. Defendants conducted business in the State of Missouri through sales representatives conducting business in the State of Missouri and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or selling, either directly or indirectly, and/or through third parties or related entities, Pelvic Mesh Products.

19. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants because Defendants are present in the State of Missouri such that requiring an appearance does not offend traditional notices of fair play and substantial justice.

III. DEFENDANTS' PELVIC MESH PRODUCTS

20. In or about 1999, the Cook Defendants began to market and sell products for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

21. Specifically, Cook Group, Incorporated, by and through its subsidiary, Cook Biotech, Inc., sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of stress urinary incontinence: Surgisis Biodesign Urethral Sling on September 23, 1999 and Surgisis Biodesign Tension-Free Urethral Sling on April 9, 2002. Cook Biotech, Inc. sought and secured 510K clearance on the following medical devices indicated and/or sold for the repair or restoration of pelvic floor repair: Surgisis Biodesign Anterior Pelvic Floor Graft; Surgisis Biodesign Posterior Pelvic Floor Graft; and Surgisis Biodesign Vaginal Erosion Repair Graft on September 23, 1999.

22. Boston Scientific promotes medical devices, including Lynx, as a surgical mesh product intended to treat stress urinary incontinence.

23. Defendants' products were derived largely from hernia mesh products, and were and are utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence.

24. The surgical mesh products manufactured by Defendants are considered Class II medical devices.

25. Under the 510(k) process, a manufacturer must provide a premarket notification that allows the FDA to determine whether the device is substantially equivalent to a "predicate device." A predicate device is one that the FDA has placed into one of three classification categories and "cleared" for marketing.

26. Unlike Class III medical devices, such as an artificial heart or an Automated External Defibrillator, Class II devices do not require "approval" by the FDA. Whereas Class III devices cannot be sold until the manufacturer demonstrates to the FDA, through adequate and well-controlled clinical trials, that the proposed device is safe and effective, there is no such requirement for Class II devices. The "premarket notification" process – for Class II devices – is not focused on whether the device is safe and effective, but rather is concerned with whether the proposed device is substantially equivalent to an existing predicate device that was already cleared for marketing by the FDA.

27. Defendant was aware, or should have been aware, of the dangers inherent in its transvaginal mesh products generally, notwithstanding the fact that these products were "cleared" for sale by the FDA.

28. On October 20 2008, the FDA issued a Public Health Notification ("PHN") entitled "Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence."

29. In the 2008 PHN, the FDA reported that it received "over 1,000 reports from nine surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI." The listed complications included: "erosion . . . infection, pain, urinary problems, and a recurrence of prolapse and/or incontinence . . . [and] bowel, bladder, and blood vessel perforation during insertion." The PHN went on to note that "vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia."

30. Although neither Defendants nor their Medical Devices were specifically identified in the PHN, a review of the relevant FDA database reveals that the FDA received multiple "adverse event reports" relating to their products.

31. Whereas the 2008 PHN described "over 1,000 reports" of complications relating to surgical mesh, the Update stated that from January 1, 2008 through December 31, 2010, "the FDA received 2,874 additional reports of complications associated with surgical mesh devices used to repair POP and SUI."

32. Plaintiff experienced many of the complications referenced in the 2011 Update, including, without limitation, pain, infections, vaginal extrusions, erosion, discharge, fever, distended abdomen, and continued incontinence.

33. Not only did the FDA Update describe more complications associated with transvaginal mesh surgeries, it called into question the benefit of using mesh products instead of traditional procedures that did not involve the use of mesh.

34. The FDA further stated that "[i]n order to better understand the use of surgical mesh for POP and SUI, [it] conducted a systematic review of the published scientific literature from 1996-2011 to evaluate its safety and effectiveness."

35. Defendants knew or should have known about the complications associated with their transvaginal mesh products, identified in the 2008 PHN and the 2011 Update.

36. Defendants knew or should have known that their transvaginal mesh products unreasonably exposed patients to great risk while conferring no benefit over traditional procedures that did not use mesh.

37. Contemporaneously with the Update, the FDA also released a publication prepared in conjunction with the Center for Devices and Radiological Health ("CDRH") entitled

"*Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse*."

38. Whereas the Update stated that the FDA performed a search of medical literature "in order to better understand the use of surgical mesh for POP and SUI," the FDA/CDRH publication stated the FDA conducted the search "due to ongoing concerns in the clinical community and the safety signals identified from adverse event reports."

39. In light of these concerns, the FDA is considering several regulatory changes regarding transvaginal mesh. These include:

- Changing the risk classification of transvaginal mesh from a Class II to a Class III device. As noted above, such a change would require manufacturers to obtain FDA "premarket approval" after providing it with clinical data showing the safety and effectiveness of a new device. Mesh manufacturers would no longer be able to market new transvaginal mesh products after simply providing the FDA with "premarket notice" that the device is equivalent to an existing predicate device;
- Conducting clinical studies to address the risks and benefits of mesh to treat POP and SUI; and
- Expanded post-market monitoring of transvaginal mesh performance.

40. According to a notice published in the *Federal Register*, The Obstetrics-Gynecology Devices Panel of the Medical Devices Advisory Committee of the FDA is scheduled meet in September 2011"to discuss the safety and effectiveness of transvaginal placement of mesh for POP and SUI procedures."

41. A review of scientific literature and other sources indicate that the defects in the mesh relate to any or all of the following:

a. the use of polypropylene material in the Mesh itself and the immune reaction that results, causing adverse reactions and injuries;

b. the design of the Pelvic Mesh Device to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury;

d. the use and design of anchors in the Pelvic Mesh Product which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

e. degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury;

f. the welding of the mesh itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike; and/or

g. the design of trocars, as devices to insert the Pelvic Mesh Product into the vagina, are defective because the device requires tissue penetration in nerve-rich environments which frequently results in the destruction of nerve endings, causing pain and other injuries.

42. Defendants' pelvic mesh products incorporate a monofilament polypropylene mesh intended for the treatment of stress urinary incontinence. Despite claims that this material is inert, the emerging scientific evidence suggests that this material is biologically incompatible

with human tissue and promotes an immune response in a large subset of the population receiving Defendants' pelvic mesh products containing this material. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

43. Defendants' pelvic mesh products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable medical devices; implanted by safe and effective minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and/or stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment and other competing pelvic mesh products.

44. Defendants have marketed and sold its pelvic mesh products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices and include the provision of valuable cash and non-cash benefits to health care providers. Also utilized are documents, brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the products.

45. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, Defendant's Medical Devices have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law. Defendants have consistently underreported and withheld information about the propensity of

their pelvic mesh products to fail and cause injury and complications and has misrepresented the efficacy and safety of its products and, through various means and media, actively and intentionally been misleading the FDA, the medical community, patients, and the public at large.

46. Defendants have known and continue to know that some of the predicate products for their Medical Devices had high failure and complication rates, resulting in the recall of some of these predicate devices; that there were and are differences between Defendants' Medical Devices and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that significant differences exist and existed between their Medical Devices and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the Medical Devices were and are causing numerous patients severe injuries and complications. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or patients. As a result, Defendants actively and intentionally misled and continues to mislead the public, including the medical community, health care providers and patients, into believing that the Medical Devices and the procedures for the implantation were and are safe and effective, leading to the prescription for and implantation of the Medical Device(s) into Plaintiff.

47. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Medical Devices.

48. Defendants failed to design and establish a safe, effective procedure for removal of their pelvic mesh products; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Medical Devices.

49. Feasible and suitable alternative designs, as well as suitable alternative procedures and instruments for implantation, have existed at all times relevant as compared to Defendants' Medical Devices.

50. The Medical Devices were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedure for implanting the device, and trained the implanting physicians.

51. Defendants provided incomplete, insufficient, and misleading training and information to physicians in order to increase the number of physicians utilizing the Medical Devices and, thus, increased the sales of the Medical Devices, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

52. The Medical Devices implanted into Plaintiff were in the same or substantially similar condition as it was when they left the possession of Defendants and in the condition directed by and expected by Defendants.

53. Plaintiff and her physicians foreseeably used and implanted Defendants' Medical Device and did not misuse or alter the Medical Devices in an unforeseeable manner.

54. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' pelvic mesh products, include without limitation: mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, the recurrent prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other

medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

55. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' pelvic mesh products, have examined each of these injuries, conditions, and complications and determined that they are, in fact, casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

56. Defendants misrepresented to the medical and healthcare community, Plaintiff, the FDA, and the public at large that the pelvic mesh products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

57. These representations were made by Defendants with the intent of inducing Plaintiff, the medical community, and the public to recommend, prescribe, dispense, and purchase the Medical Device for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced an indifference to the health, safety, and welfare of Plaintiff.

58. Defendants acted unreasonably in failing to undertake its duties to properly know the qualities of their products and in representations to Plaintiff and/or to Plaintiff's healthcare providers and concealed and intentionally omitted the following material information:

a) That the Medical Device was not as safe as other products and procedures available to treat incontinence and/or prolapse;

b) That the risk of adverse events with the Medical Device was higher than with other products and procedures available to treat incontinence and/or prolapse;

c) That the risk of adverse events with the Medical Device was not adequately tested and were known by Defendants;

d) That the limited clinical testing revealed the Medical Device had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e) That Defendants failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

f) That Defendants were aware of dangers in its pelvic mesh products, in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

g) That pelvic mesh systems were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

h) That patients frequently would need revisionary surgery due to changes in the structure of the Medical Device that would cause it to be become loose or shift position within the body.

i) That patients needed to be monitored more regularly than usual while using the Medical Device and that in the event the product needed to be removed that the procedure to remove them had a very high failure rate and/or needed to be performed repeatedly.

59. Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of the Medical Devices, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

60. Defendants had sole access to material facts concerning the defective nature of the Medical Device and its propensity to cause serious and dangerous side effects and, hence, cause dangerous injuries and damage to persons who used the Medical Device.

61. Defendants' concealment and omissions of material facts concerning the safety of its pelvic mesh products were made to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Medical Device and/or to mislead Plaintiff into reliance and cause Plaintiff to use the Medical Device.

62. At the time these representations were made by Defendants, and at the time Plaintiff used the Medical Device, she was unaware of the falsehood of these representations and reasonably believed them to be true.

63. Defendants knew and had reason to know that the Medical Device could and would cause severe and grievous personal injury to its users and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

64. In reliance upon these false representations, Plaintiff was induced to, and did, use the Medical Device thereby sustaining severe and permanent personal injuries and damages.

65. Defendants knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions and that these included material omissions of facts surrounding the use of the Medical Device(s), as described in detail herein.

66. As a result of Defendants' research and testing or lack thereof, they distributed false information including, but not limited to, assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians that the Medical Device was safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and was as safe or safer than

other products and/or procedures available and on the market. As a result of Defendants' research and testing or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiff, and the public at large.

67. Defendants had a duty when disseminating information to the public to disseminate truthful information;] and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the FDA.

68. The information distributed to the public, the medical community, the FDA, and Plaintiff by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Medical Device.

69. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Medical Device specifically that it did not have dangerous and/or serious adverse health safety concerns and that it was as safe as other means of treating stress urinary incontinence and/or prolapse.

70. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate, including erosion, the difficulty of removing the Medical Device, and the risk of permanent injury.

71. Defendants chose to over-promote the safety, efficacy and benefits of the Medical Devices instead.

72. Defendants' intent and purpose in making these misrepresentations was to deceive the public, the medical community, and Plaintiff; to gain the confidence of the public, the

medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Medical Device; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Medical Device.

73. Defendants made claims and representations in documents they submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Medical Device did not present serious health risks.

74. These representations, and others made by Defendants were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist and were made recklessly and without regard to the true facts.

75. These representations, and others made by Defendants were made with the intention of deceiving Plaintiff, Plaintiff's healthcare professionals, and other members of the healthcare community and were made in order to induce Plaintiff and her healthcare professionals to rely on misrepresentations and caused Plaintiff to purchase, rely, use, and request the Medical Device and her healthcare professionals to dispense, recommend, or prescribe the Medical Device.

76. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Medical Devices to the public at large for the purpose of influencing the sales of product known to be dangerous and defective and/or not as safe as other alternatives.

77. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Medical Devices.

78. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the

use of the Medical Device(s). Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendant's misrepresentations.

79. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Defendants' Medical Device(s), she would not have purchased, used, or relied on Defendants' Medical Device(s).

80. The Cook Defendants' make the following assertions regarding their products:

> Surgisis Biodesign is not a new- graft or mesh, but a whole new category in the evolution of tissue repair. A breakthrough technology, it incorporates the best attributes of a biologic graft—**resistant to infection and complete remodeling**—with the added benefits of moderate price, ease of use and widespread availability. Surgisis Biodesign offers you a new level of assurance and, most important, contributes to an improved quality of life for your patient. http://www.cookmedical.com/bioNew/bio_overview.html.

81. The Cook Defendants' further assert the following about their Biodesign products: "And unlike synthetic mesh, **nothing is left permanently in the body to cause problems down the road**." http://www.cookbiodesign.com/for-patients/conditions/fistula/faqs.

82. On August 20, 2011, the Cook Defendants issued a communication to the FDA in advance of the September 2011 Advisory Committee Hearings regarding the investigation into the risks associated with mesh for stress urinary incontinence and pelvic floor repair and/or pelvic floor prolapse. In its communication, the Cook Defendants assert regarding its non-cross linked biologic matrix that: "[**a]ny inflammation is localized in regions where small remnants of the synthetic suture used to affix the graft remain**."

83. Contrary to the Cook Defendants' assertions that its products are resistant to infection; result in complete remodeling, are limited in inflammatory response to area where

synthetic sutures are/were utilized during surgery and will not cause any problem down the road, the following non-inclusive literature suggests otherwise:

A. In November of 2005, results from a study were published in the International Journal of Obstetrics & Gynecology relating to the comparison of the host response, architectural integration and tensile strength of polypropylene to porcine small intestine submucosa-derived implants including Defendants SIS products. Implants from the SIS group showed a short term increase in thickness in the first 14 days. **Formation of adhesions was significantly more extensive in the SIS group at 90 days. Tensile strength increased over time in both groups but was significantly lower in the SIS group. Implants in the SIS group showed inflammatory response.**

   Konstantinovic ML., Lagae P., Zheng F., Verbeken EK., De Ridder D., Deprest JA. (2005). Comparison of host response to polypropylene and non-cross-linked porcine small intestine serosal-derived collagen implants in a rat model. *BJOG: An International Journal of Obstetrics & Gynecology*, 112(11),1554-1560.

B. In October of 2008, results from a study were published in the Archives of Gastroenterology relating to the comparison of the repair of induced abdominal wall defects with Defendants' Surgisis mesh and Covidien, Inc.'s Parietex. Both meshes induced skin erosions. There were peritoneal adhesions to the surface of both types of meshes after 30 and 60 days. **Meshes' shrinking correspond to 1/3 of the original size and Parietex caused less inflammatory process at the histologic evaluation**.

   Baroncello JB., Czeczko NG., Malafaia O., Ribas-Filho JM., Nassif PA., Dietz AU. (2008). [The repair of abdominal defects in rabbits with Parietex and Surgisis meshes abdominal wall]. *Arquivos de Gastroenterologia*, 45(4), 323-9.

C. In November of 2008, results from a study were published in Urology relating to reports of intense local inflammatory reactions in patients undergoing pubovaginal sling or tape using a small intestinal submucosa graft. **After implantation of 16 standard pubovaginal sling or tension-free tape procedures for stress urinary incontinence, using the Cook 4-ply Stratasis or 8-ply Stratasis-TF system, 5 (31.3%) had intense suprapubic pain after surgery. One patient had induration of the mons pubis that required surgical drainage. One patient had vaginal inflammation, with expulsion of graft material. Other patients had intense rectus sheath inflammation, as confirmed on computed tomography. This study confirmed previous case reports of inflammatory complications of small intestinal submucosa leading to that institution's cessation of use of Defendants' products**.

   John TT., Aggarwal N., Singla AK., Santucci RA. (2008). Intense inflammatory reaction with porcine small intestine submucosa pubovaginal sling or tape for stress urinary incontinence. *Urology*, 72(5), 1036-9.

D. In January of 2009, results from a study were published in the Journal of Biomedical Materials Research Part B relating to the evaluation of Defendants' Surgisis Gold to other materials including C.R. Bard, Inc.'s Permacol; Ethicon's Prolene mesh and Life Cell's Alloderm in the context of human mesothelial cells. **The results of the study indicate that Surgisis Gold was inferior in aiding in the growth and fibrinolytic activity of human mesothelial cells than other products.**

Wilshaw SP., Burke D., Fisher J., Ingham E. (2009). Investigation of the antiadhesive properties of human mesothelial cells cultured in vitro on implantable surgical materials. *Journal of Biomedical Materials Research Part D: Applied Biomaterials,* 88(1), 49-60.

E. In October of 2011, results from a study were published in the Archives of Gastroenterology relating to the comparison of different biologic materials regarding relative implant integration, shrinkage, and foreign body reaction. Relating to **Defendants' Surgisis, the integration of its product was insufficient and could detached easily from the underlying tissue; the penetration of fibroblasts and vessels was limited; foreign body reaction was pronounced, leading to persistent granulomatous inflammation; and shrinkage was excessive in comparison to all other products. Other products yielded sufficient anti-adhesion and elicited no foreign body reaction.**

Petter-Puchner AH.**,** Fortelny RH., Silic K, Brand J., Gruber-Blum S., Redl H. (2011). Biologic hernia implants in experimental intraperitoneal onlay mesh plasty repair: the impact of proprietary collagen processing methods and fibrin sealant application on tissue integration. *Surg Endosc,* 25(10), 3245-52.

F. In February of 2012, results from a study were published in Hernia relating to the comparison of different biologic meshes including Defendants' Surgisis Gold regarding the relative performance and efficacy as between two non-crosslinked meshes and two crosslinked prostheses. **Major complications seen with Defendants' product included: that it appeared to be wrinkled and folded by excessive shrinkage, eliciting severe adhesions and a pronounced local inflammation, characterized by foreign body giant cells. The multilayer design was preserved but disintegrated by transversal movement of layers against each other**.

de Castro Brás LE., Shurey, S., Sibbons, PD. (2012). Evaluation of crosslinked and non-crosslinked biologic prostheses for abdominal hernia repair. *Hernia,* 16(1), 77-89.

G. In September of 2012, results from a study were published in Biomaterials relating to the clinical performance of biomaterials in the context of comparing leukocyte activation by commercially available biologic surgical materials and define the extent manufacturing variables influence down-stream response. The data demonstrated

Defendants' Surgisis Biodesign which was implanted in Plaintiff showed excessive leukocyte activation and was significantly more pro-inflammatory as compared to the other products analyzed. High degrees of leukocyte activation lead to poor material/patient compliance, accelerated degeneration and graft rejection.

Bryan N., Ashwin H., Smart N., Bayon Y., Scarborough N., Hunt JA. (2012). The innate oxygen dependant immune pathway as a sensitive parameter to predict the performance of biological graft materials. *Biomaterials*, 33(27), 6380-92.

IV. FACTUAL BACKGROUND

84. On or about December 30, 2009, Plaintiff was implanted with the Cook Surgisis and Boston Scientific Lynx ("Pelvic Mesh Products" and/or "Product") during surgery performed in Huntsville, Alabama.

85. The Products were implanted in Plaintiff to treat her stress urinary incontinence, the use for which the Products were designed, marketed and sold.

86. As a result of having the Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, permanent and substantial physical deformity, has undergone and will undergo corrective surgery or surgeries, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

87. Defendants' Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

88. The Defendants have marketed and sold the Defendants' Pelvic Mesh Products to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, and telephone information lines, offering exaggerated and misleading expectations as to the safety and utility of the Defendants' Pelvic Mesh Products.

89. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff.

90. The Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

91. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the

Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Defendants' Pelvic Mesh Products were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into the Plaintiff.

92. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' Pelvic Mesh Products.

93. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' Pelvic Mesh Products; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' Pelvic Mesh Products.

94. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

95. The Defendants' Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendants.

96. The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Pelvic Mesh Products, and thus increase the sales of the Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

97. The Pelvic Mesh Products implanted into the Plaintiff was in the same or substantially similar condition as they were when they left the possession of Defendants, and in the condition directed by and expected by the Defendants.

98. The injuries, conditions, and complications suffered due to Defendants' Pelvic Mesh Products include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to Plaintiff's intimate partners.

99. Despite Defendants' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Products, the Defendants have, and continue to manufacture, market, and sell the Products, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to the Defendants' Pelvic Mesh Products, both prior to and after the marketing and sale of the Products.

100. Plaintiff in the exercise of due diligence, could not have reasonably discovered the cause of her injuries including but not limited to the defective design and/or manufacturing of the products implanted inside of her until recently.

COUNT I

PRODUCT LIABILITY ACT – FAILURE TO WARN

101. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

102. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants' Pelvic Mesh Products.

103. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the risks and benefits of the Defendants' Pelvic Mesh Products, given the Plaintiff's conditions and need for information.

104. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Products, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products.

105. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Pelvic Mesh Products, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

106. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

107. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct.

WHEREFORE, Plaintiff demands judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT II

STRICT LIABILITY

108. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

109. At the time of Plaintiff's injuries, the Defendants' Pelvic Mesh Products were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiff, and the warnings labels and instructions were deficient.

110. Plaintiff adopts the *Restatement of Torts (Second)* and/or the *Restatement of Torts (Third),* bringing strict product liability claims under the common law, *Section 402A of the Restatement of Torts (Second), and/or Restatement of Torts (Third))* against Defendants.

111. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III

NEGLIGENCE

112. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

113. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' Pelvic Mesh Products, and recruitment and training of physicians to implant the Pelvic Mesh Products.

114. Defendants breached their duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the Pelvic Mesh Products.

115. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, Plaintiff has been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV

NEGLIGENT MISREPRESENTATION

116. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

117. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Pelvic Mesh Products had not been

adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

118. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

119. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

120. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

121. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V

NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

122. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

123. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Pelvic Mesh Products to Plaintiff, carelessly and negligently concealing the harmful effects of the Defendants' Pelvic Mesh Products from Plaintiff, and carelessly and negligently misrepresented the quality, safety and efficacy of the products.

124. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the Pelvic Mesh Products sold and distributed by Defendants.

125. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI

BREACH OF EXPRESS WARRANTY

126. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

127. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Products.

128. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Products be used in the manner that Plaintiff in fact used them and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other pelvic mesh products, and that it was adequately tested and fit for its intended use.

129. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the Pelvic Mesh Products; which is to say that Plaintiff was a foreseeable user of the Defendants' Pelvic Mesh Products.

130. Plaintiff and/or her implanting physicians were at all relevant times in privity with Defendants.

131. The Defendants' Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

132. Defendants breached various express warranties with respect to the Pelvic Mesh Products including the following particulars:

Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Products;

1. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Pelvic Mesh Products were as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Products were not safer than alternatives available on the market; and

2. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Pelvic Mesh Products were more efficacious than other alternative medications and fraudulently concealed information, regarding the true efficacy of the products.

133. In reliance upon Defendants' express warranty, Plaintiff was implanted with the Defendants' Pelvic Mesh Products as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

134. At the time of making such express warranties, Defendants knew or should have known that the Defendants' Pelvic Mesh Products do not conform to these express representations because the Defendants' Pelvic Mesh Products were not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Pelvic Mesh Products unreasonably unsafe for their intended purpose.

135. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the Public relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Defendants' Pelvic Mesh Products.

136. Defendants breached their express warranties to Plaintiff in that the Defendants' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended uses, nor were they adequately tested.

137. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII

BREACH OF IMPLIED WARRANTY

138. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

139. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Products.

140. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Products be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used them and Defendants impliedly warranted each product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

141. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant the Defendants' Pelvic Mesh Products in the manner directed by the instructions for use; which is to say that Plaintiff were foreseeable users of the Defendants' Pelvic Mesh Products.

142. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

143. The Defendants' Pelvic Mesh Products were expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which they were manufactured and sold by Defendants.

144. Defendants breached various implied warranties with respect to the Defendants' Pelvic Mesh Products, including the following particulars:

> Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Products were safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Products;

1. Defendants represented that the Defendants' Pelvic Mesh Products were safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Defendants' Pelvic Mesh Products were not as safe or safer than alternatives available on the market; and

2. Defendants represented that the Defendants' Pelvic Mesh Products were more efficacious than alternative pelvic mesh products and procedures and fraudulently concealed information, regarding the true efficacy of the Defendants' Pelvic Mesh Products.

145. In reliance upon Defendants' implied warranty, Plaintiff used the Pelvic Mesh Products as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

146. Defendants breached their implied warranty to Plaintiff in that the Defendants' Pelvic Mesh Products were not of merchantable quality, safe and fit for their intended use, or adequately tested.

147. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII

VIOLATION OF CONSUMER PROTECTION LAWS

148. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

149. Plaintiff purchased and used the Defendants' Pelvic Mesh Products primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

150. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' Pelvic Mesh Products, and would not have incurred related medical costs and injury.

151. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pelvic Mesh Products that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

152. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a.) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b.) Advertising goods or services with the intent not to sell them as advertised; and,

c.) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

153. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Pelvic Mesh Products. Each aspect

of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Products.

154. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Products.

155. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Products, and would not have incurred related medical costs.

156. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

157. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

158. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

- 15 U.S.C. §§ 2301-2312 (1982);

159. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

160. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices

and false advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh Products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

161. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

162. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Products and failed to take any action to cure such defective and dangerous conditions.

163. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

164. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

165. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

166. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests restitution and disgorgement of

profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT IX

GROSS NEGLIGENCE

167. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

168. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

169. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

170. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

171. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X

UNJUST ENRICHMENT

172. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

173. Defendants are and at all times were the manufacturers, sellers, and/or suppliers of the Defendants' Pelvic Mesh Products.

174. Plaintiff paid for the Defendants' Pelvic Mesh Products for the purpose of treatment of stress urinary incontinence and/or pelvic organ prolapse or other similar condition.

175. Defendants have accepted payment by Plaintiff and others on Plaintiff's behalf for the purchase of the Defendants' Pelvic Mesh Products.

176. Plaintiff has not received the safe and effective medical devices for which she paid.

177. It would be inequitable for Defendants to keep this money since Plaintiff did not in fact receive a safe and effective medical device.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XI

PUNITIVE DAMAGES

178. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

179. At all times relevant hereto, Defendants knew or should have known that the Defendants' Pelvic Mesh Products were inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

180. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Defendants' Pelvic Mesh Products.

181. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Defendants' Pelvic Mesh Products.

182. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' Pelvic Mesh Products cause debilitating and potentially lethal side effects

with greater frequency than safer alternative methods products and/or procedures and/or treatment.

183. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' Pelvic Mesh Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same.

184. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk of injuries caused by the Defendants' Pelvic Mesh Products.

185. Notwithstanding the foregoing, Defendants continue to aggressively market the Defendants' Pelvic Mesh Products to consumers, without disclosing the true risk of side effects where there were safer alternatives.

186. Defendants knew of the Defendants' Pelvic Mesh Products defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Defendants' Pelvic Mesh Products so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Defendants' Pelvic Mesh Products.

187. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Defendants' Pelvic Mesh Products in order to ensure continued and increased sales.

188. Defendants' intentionally reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable them to weigh the true risks of using the Defendants' Pelvic Mesh Products against their benefits.

189. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services, and has incurred medical, health care, incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

190. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages pursuant Common Law principles.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII:

LOSS OF CONSORTIUM

191. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if fully set forth herein.

192. Plaintiff CHRIS MYERS is the spouse of Plaintiff, ELENA MYERS, as a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff, CHRIS MYERS has necessarily paid and has become liable to pay for medical aid, treatment, attendance and medications, and will necessarily further expenses of a similar nature in the future.

193. As a direct and proximate result of the above-described injuries sustained by Plaintiff, ELENA MYERS, her husband, Plaintiff, CHRIS MYERS has suffered a loss of his wife's consortium, companionship, society, affection, services and support.

194. AS a direct and proximate result of Defendants' conduct as described in this Complaint, Plaintiff, CHRIS MYERS has suffered physical harm and injury as a result of the Defendants' product as well as other damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

i. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

ii. Reasonable attorneys' fees;

iii. The costs of these proceedings;

iv. All ascertainable economic damages;

v. Punitive damages;

vi. Loss of Consortium; and

vii. Such other and further relief as this Court deems just and proper.

Dated: February 14, 2013

By: /s/ Jeffrey M. Kuntz

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JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues.

By: /s/ Jeffrey M. Kuntz
Jeffrey M. Kuntz
WAGSTAFF & CARTMELL, LLP
Attorneys for Plaintiff